



Department of Energy
Washington, DC 20585

January 5, 2007

MEMORANDUM FOR THE DEPUTY SECRETARY

THROUGH:

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SUBJECT:

2006 Report on Quality Assurance throughout the
Department of Energy

On April 26, 2006, the Secretary requested all Departmental Elements report on their implementation of Department of Energy (DOE) Order (O) 414.1C, *Quality Assurance*. The Secretary expressed concern with the findings of various external stakeholders, namely the General Accountability Office, and the Department's Inspector General, at what was reported as inconsistent implementation of quality assurance policies and principles.

Reporting guidance was developed by an interoffice working group, and Departmental Elements were requested to report their progress in developing and implementing quality assurance programs. On September 22, 2006, a preliminary status report was provided to you on the survey results received to date. In an effort to provide a more complete report, those Departmental Elements not responding to the original request were contacted and given the opportunity to submit their input. As a result, further responses were received and incorporated into this report.

In summary, a number of Headquarters (HQ) offices reported that they do not have a written Quality Assurance Program (QAP) in place, but are in the process of developing one as required by DOE O 414.1C. Most field offices reported that they and their contractors have a QAP in place, although some may not be in compliance with this Order. Those that reported they were not in compliance are either 1) in the process of updating their QAPs; 2) governed by external agencies (e.g., Nuclear Regulatory Commission) applying other quality assurance (QA) requirements; or 3) exempted because the Order is not applicable to their missions. In addition, most HQ offices and field offices reported they have designated a manager responsible for QA, and have programs in place for quality assessment and improvement.



The attached final report provides detailed information on the responses to the survey and where the Department stands in adopting a QA culture. This is the first step in assessing the implementation of the Department's QA program. Later in FY 2007, more specific guidance to measure the effectiveness of QA implementation will be provided to Departmental Elements. This will support annual reporting as required by DOE O 414.1C. The Office of Health, Safety and Security (HSS) is committed to working with Departmental Elements to achieve a robust QA program for the Department. In furtherance of that goal, HSS and the Office of Management are in discussion about recombining corporate QA responsibilities that were divided upon creation of HSS. We will brief you further on that organizational proposal in the near future.

If you have any questions regarding the report or the survey process, please contact me directly at (301) 903-8008.

Attachment

SUBJECT: 2006 Report on Quality Assurance throughout the Department of Energy

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2006 Report on the Implementation of
Quality Assurance throughout the
Department of Energy



December 2006

**U.S. Department of Energy
Office of Health, Safety and Security
Office of Corporate Safety Analysis**

OFFICE OF CORPORATE SAFETY ANALYSIS

**2006 REPORT ON THE IMPLEMENTATION OF
QUALITY ASSURANCE THROUGHOUT THE
DEPARTMENT OF ENERGY**

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EXECUTIVE SUMMARY

In his memorandum "Improving Quality Assurance," dated April 26, 2006, the Secretary of Energy stated the Department's priority of implementing an effective Quality Assurance (QA) program and promulgating a quality culture throughout the Department of Energy (DOE) complex. The Secretary acknowledged the negative impacts on the DOE mission when quality is not applied consistently to Departmental programs. These impacts include rework, delays, and increased program costs in addition to increased risk to workers and the environment. Furthermore, internal and external reviews by the Department's Inspector General (IG) and the General Accountability Office (GAO) pointed to inconsistent implementation of quality assurance (QA) policies and principles.

The Secretary directed all Departmental Elements to report on their QA implementation to the former Office of Environment, Safety and Health to assess the status of the Department's written QA Programs (QAPs). The results of this survey highlight for the Secretary the progress made by Headquarters (HQ) and the Field thus far in implementing quality, as well as the work ahead to develop and strengthen a quality culture within the Department.

There is evidence that the Department is making great strides in bringing itself into compliance with the DOE O 414.1C, *Quality Assurance*. One of the most notable outcomes of this survey is that it heightened senior management attention to the Order and prompted several HQ and Field Offices (FOs) to develop or begin developing their QAPs.

While the Order does allow organizations to apply a graded approach in developing and executing their QAPs, some of those recently developed appear to fall short of the requirements in the Order. This may be a result of the organizations not understanding the QA criteria. Some organizations also found it difficult to apply the QA criteria to their offices' missions, especially since the majority of HQ work is administrative in nature.

In summary, a number of HQ offices reported that they do not have a written QAP in place, but are in the process of developing one as required by DOE O 414.1C. Most FOs reported that they and their contractors have a QAP in place, although some may not be in compliance with this Order. Those that reported they were not in compliance are either 1) in the process of updating their QAP per this Order; 2) governed by external agencies (e.g., Nuclear Regulatory Commission) applying other QA requirements; or 3) exempted because this Order is not applicable to their mission. In addition, most HQ offices and FOs reported they have designated a manager responsible for QA, and have programs in place for assessment and improvement.

This final report provides detailed information on the response to the survey and where the Department stands in adopting a QA culture. This is the first step in assessing the implementation of the Department's overall QA program. Later in FY 2007 more specific guidance to measure the effectiveness of QA implementation will be provided to Departmental Elements. This will support annual reporting as required by DOE Order 414.1C. The Office

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of Health, Safety and Security is committed to working with Departmental Elements to achieve a robust QA program for the Department.

INTRODUCTION

Quality assurance is a system of management activities to support planning, organization, resources, direction, and control to ensure that the DOE, including National Nuclear Security Administration (NNSA), products and services meet or exceed customers' expectations.

With only two exceptions,¹ DOE Order 414.1C, *Quality Assurance*, requires each DOE organization to develop and implement a written QAP that integrates specified quality requirements in accordance with several national or international consensus standards, including title 10 CFR 830, Subpart A, *Quality Assurance Requirements*.

The purpose of this report is to provide an overview of where the Department stands in terms of implementing QA complex-wide. The report also provides a path forward for further QA effectiveness reviews to ensure that all HQ and Field Elements are in compliance with DOE Order 414.1C.

BACKGROUND

In his memorandum "Improving Quality Assurance," dated April 26, 2006, the Secretary of Energy stated the Department's priority of implementing an effective QA program and promulgating a quality culture throughout the DOE. The Secretary acknowledged the negative impacts on the DOE mission when quality is not applied consistently to Departmental programs. These impacts include rework, delays, and increased program costs in addition to increased risk to workers and the environment. Furthermore, internal and external reviews by the IG and GAO pointed to inconsistent implementation of QA policies and principles.

The Secretary directed all Departmental Elements to report on their QA implementation to the former Office of Environment, Safety and Health (EH) to assess the status of the Department's QAPs. A working group led by EH and comprised of HQ and Field representatives from the Office of Environmental Management, Office of Science, Office of Nuclear Energy, Office of Fossil Energy and NNSA developed reporting guidance to gather information to begin to assess the status of the Department's QAPs and to identify areas for improvement.

The Quality Assurance Implementation Reporting Guidance was designed to collect basic compliance information about the status of QA implementation based on each element's QAP and primarily delved into four areas of QA. It focused on the status of Departmental

¹This Order does not apply to the DOE/NNSA Naval Reactors Program in accordance with Executive Order 12344, or to the Bonneville Power Administration (BPA) in accordance with Secretarial delegation Order Number 00-033.00A to the BPA Administrator and Chief Executive Officer.

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Elements having QAPs developed and approved per DOE Order 414.1C; QA authorities and qualifications status; assessment and improvement activities; and flow-down of QA requirements to Field Elements and contractors. The areas selected are basic elements of a QAP and provide insight on the implementation of the Department's program and allow for future evaluation of the status of QA across the DOE.

Several of the HQ organizations originally identified as accountable under the current Order (revised in June 2005) have been dissolved, merged, or otherwise reorganized. The survey, distributed in June 2006, was sent to 29 applicable DOE organizations. An interim report of the initial survey responses was prepared for the Deputy Secretary and published in September 2006. As of November 22, 2006, 26 of the original 29 and 35 of their associated Field Elements have now responded to the survey. An annotated list of the responding offices is included as Attachment A. The results in this report are based on the responses received as of this date.

In the intervening months since the working group received the survey responses and delivered the interim report, the Department created the new Office of Health, Safety and Security (HSS), which has subsumed several of the offices that were on the survey distribution. These elements were the Office of the Departmental Representative to the Defense Nuclear Facilities Safety Board (DNFSB), EH, and the Office of Security and Safety Performance Assurance. Therefore, in future analyses, 27 offices will be accountable for complying with the Order.

After the initial responses were received, the review team contacted all other Departmental Elements that did not respond to determine their status. The team wanted to give these offices every opportunity to be counted. Responses from several offices have been added since the interim report.

The Office of Corporate Safety Analysis, within HSS, collected, analyzed, and compiled the inputs from the various Departmental Elements and presents the results of the Department's implementation of QA in this final report. This initial round of survey reporting is the first step in assessing the state of QAPs in the Department. It does not as yet provide a clear picture of the effectiveness of the QAPs that have been developed or the implementation of those programs.

An interoffice working group led by HSS has developed a tentative plan and schedule for conducting more in-depth analyses of QA effectiveness over the next few years. Starting in FY 2007, the working group will develop more specific guidance to allow line management to measure the effectiveness of QA implementation and provide annual reports as required by DOE Order 414.1C. The results from future effectiveness reviews will be essential for the Order review tentatively scheduled in calendar year 2007.

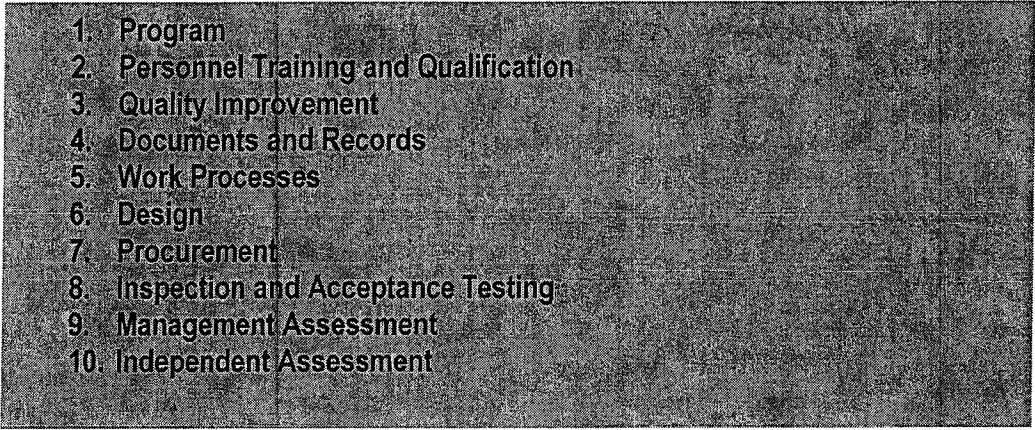
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Overview of DOE Order 414.1C Requirements

DOE Order 414.1C was promulgated to ensure that DOE, including NNSA, products and services meet or exceed customers' expectations. The Order further states that QA must be applied to all work based on the several guiding principles as follows:

1. Quality is assured and maintained through a single, integrated, effective QAP (i.e., management system);
2. Management support/functions are essential to QA
3. Performance and quality improvement require thorough, rigorous assessment and corrective action;
4. Workers are responsible for achieving and maintaining quality; and
5. Risks to the worker, public, and environment may be minimized at the same time work performance and product reliability may be maximized.

All primary DOE organizations and their associated Field Elements are required to develop and implement a QAP in accordance with the DOE Order 414.1C. The Order stipulates ten QA criteria that must be addressed in QAPs and their implementing plans. These ten criteria, categorized as management, performance, or assessment activities, are as follows:

- 
1. Program
 2. Personnel Training and Qualification
 3. Quality Improvement
 4. Documents and Records
 5. Work Processes
 6. Design
 7. Procurement
 8. Inspection and Acceptance Testing
 9. Management Assessment
 10. Independent Assessment

RESULTS OF QA SURVEY

The 2006 Quality Assurance Implementation survey was designed to gather rudimentary information regarding the QAPs and procedures for each Departmental Element. Five QA criteria were examined in this first round analysis: program; training and qualification; quality improvement; management assessment; and independent assessment. The specific survey questions and associated reports by the 26 offices that responded to the inquiry are described in the following sections. Summary statistical data is provided in Appendix B.

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QA Program – General Requirements (Criterion 1)

- a. Has the Secretarial Office (SO) QAP for HQ been developed and approved per DOE Order 414.1C?
- b. Have all the Field Office (FO) QAPs been developed and approved per DOE Order 414.1C?
- c. Have all implementation procedures been written and approved for implementation?

The survey responses indicate that 17 Departmental Elements have developed and approved a QAP and 27 FOs have an approved QAP in place. In response to the Secretary's memorandum, nine Departmental Elements reported either their intent to develop a QAP in accordance with the Order or that they did not have a QAP. These elements were:

- Chief Financial Officer
- Office of Congressional and Intergovernmental Affairs
- Office of Energy Information Administration
- Office of Human Capital Management,
- Office of Hearings and Appeals,
- Office of Electricity Delivery and Energy Reliability,
- Office of Management and
- Office of Policy and International Affairs
- Office of Public Affairs

Four FOs also reported that they will develop a draft QAP with approval anticipated next year. These were:

- Berkeley Site Office
- Consolidated Business Center
- Grand Junction Office
- Rocky Mountain Oilfield Testing Center

Not all of the responses to the basic question, "Has the SO QAP for HQ been developed and approved..." were clearly answered as "Yes" or "No" for various reasons. Several of the offices identified existing QA practices and guiding principles although they may not have had a formalized QAP and program plan. The Office of the Chief Financial Officer (CFO), for instance, presented a QA Plan Crosswalk that mapped the requirements of DOE Order 414.1C against the CFO directives and underlying legislation governing it. While the CFO has concluded that its systems, procedures and directives satisfy DOE Order 414.1C, the review team interpreted this as a reply to the negative.

In another instance, the results from the Office of Management (MA) are unique in that each of its seven subcomponent offices reported individually on their compliance. Three of MA's offices have a QAP and implementing procedures in place; four either have a QAP planned or in development, or state that a QAP is not applicable to their work. The MA organization, however, does not have an overarching QAP in place.

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Some of the Departmental Elements that were dissolved or absorbed into HSS did report having a QAP, but those plans will be superseded and/or incorporated into the new HSS QAP to be developed in the coming months. These are, however, still included in this analysis.

DOE Order 414.1C allows a graded approach to be applied based on the applicability of the QA criteria to the work performed by that organization. The Order also requires implementing procedures to be written and approved. Of the applicable Departmental Elements responding, 9 HQ elements and 17 FOs have reported that procedures are in place to implement the QAP. NNSA reported that implementing procedures for HQ and their eight FOs are in the final stages of peer review. The Departmental Elements currently developing their QAPs will also have implementing procedures.

Contractor QA Implementation and Compliance (Flowdown) (Criteria 1, 7)

- a. Has the contracting officer directed that DOE Order 414.1C be added and incorporated into all applicable contracts?
- b. Has DOE approved contractor QAPs incorporating DOE Order 414.1C?

The second part of the survey pertained to the flow down of QA requirements from Federal management to contractors. The contracting officer is responsible for ensuring the Order requirements are included in the request for proposal and subsequent contract. Contracting officers have directed that 60 of 97 contractors incorporate DOE Order 414.1C into their contracts. Of these, 49 contractors have approved QAPs in place that incorporate the QA requirements contained in DOE Order 414.1C. In terms of flowing down QA requirements, the numbers maybe somewhat misleading in that:

- Some contractors reported having DOE Order 414.1B in their contracts and are currently reviewing DOE Order 414.1C for potential inclusion in their contract modifications
- Some contractors are governed under NRC regulations
- Work performed by some contractors is not applicable to DOE Order 414.1C.

Management, Training, and Qualifications (Criterion 2)

- a. Does the QAP identify the senior management position(s) and reporting structure/relationship for the person specifically assigned the responsibility to develop, approve, and implement QAPs governing the work of their organization(s) and their contractors?
- b. Does the QAP identify delegation of QAP authorities from the senior manager position to an individual (e.g., QA Manager) with authority and qualifications (i.e., QA Functional Area Standard per the DOE Technical Qualification Program, or other qualification programs) needed to carry out responsibilities (with QA performance elements in their

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performance plans) including participation in the establishment of requirements, development, assessment, oversight, and implementation of programs, projects and goals and contracts?

Part three of the survey asked about the authorities and qualifications of DOE managers with the responsibility for QA implementation. When asked if the Departmental Element's QAP identified a senior manager responsible for developing, approving, and implementing QAPs governing the work of the organization and its respective contractors, 18 Departmental Elements and 31 FOs responded positively.

This part of the survey also asked if the QA authority was delegated. Sixteen Departmental Elements and 26 FO senior managers had delegated this authority to a staff member who possessed the qualifications for QA oversight. QA authorities and qualifications should also be addressed in the 13 Field and HQ QAPs under development listed above.

Assessment and Improvement (Criteria 3, 9, and 10)

- a. Does the QAP establish Independent Assessment and Management Assessment processes with approved implementation schedules to measure the effectiveness of QA policy and program implementation in your organization?
- b. Does the QAP establish a process to identify and track actions resulting from assessments and ensure necessary improvements are achieved (i.e., a feedback and improvement or corrective action process)?

The fourth part of the survey covered the assessment and quality improvement processes of Departmental Elements. Both management and independent assessments are specified as criteria in DOE Order 414.1C. Seventeen Departmental Elements reported they had an assessment process and schedule in place to review their programs. The FOs are further ahead in implementing this requirement with 30 reporting a proactive assessment process.

As part of quality improvement, the survey asked about the implementation of a formalized corrective action tracking system. Seventeen Departmental Elements reported utilizing such a system. The number of offices having an assessment process and corrective action program does not exactly correspond. The Office of Legacy Management reported having an assessment process in place, but utilizes its contractor's corrective action process. Also, while it does not have a formal QAP and management assessment process, the CFO reported having a "full range of measures for tracking corrective actions taken in response to management and independent reviews of financial management matters." The FOs reported a more focused management of their identified corrective actions with 32 having a tracking system in place. Further improvement in this area is anticipated once the 13 QAPs under development are approved and implemented.

PATH FORWARD FOR QA EFFECTIVENESS REVIEWS

At a minimum, the effectiveness of an organization's QAP may be identified by several key indicators. These include:

- Effective and efficient mission completion within scope, schedule, and cost, and with minimum rework
- Exemplary safety performance
- Clear communications throughout the organization
- Fully trained staff with capabilities that meet or exceed job requirements
- Complete traceability of requirements down to the product through a documented QAP
- Effective corrective action and lessons learned programs

It is the Secretary's expectation that the Department continue to evaluate QAP maturity and effectiveness. In this first review year, the working group developed initial reporting guidelines with the understanding that it would use feedback from the survey responses to refine and expand the next round of guidance. Over time, surveys will also be adapted to look more closely at issues arising from independent assessments, Price-Anderson Amendment Act input, Central Technical Authority input, GAO reports, and DNFSB queries. To fulfill the requirements of the Order, these surveys will be the means whereby all Departmental Elements report annually their QAP effectiveness.

The responsibilities for the DOE QA program fall under the new HSS office, which incorporated many components of the former EH. HSS will implement future phases of the QA effectiveness review. A new QA working group consisting of HSS and other Departmental Elements will be formed in the near future to develop the next revision of the guidance for the annual reporting in calendar year 2007.

To bring all Departmental Elements into compliance with QAP requirements, HSS is committed to working with all other Departmental Elements and is available to assist in interpreting the Order to improve or develop QAPs specific to individual missions and the overall DOE mission.

CONCLUSIONS

There is evidence that the Department is making great strides in bringing itself into compliance with the Order. One of the most notable outcomes of this survey is that it heightened senior management attention to QA and prompted several HQ and FOs to develop or begin developing their QAPs.

While the Order does allow organizations to apply a graded approach in developing and executing their QAPs, some of those recently developed appear to fall short of the requirements in the Order. This may be a result of the organizations not understanding the QA criteria. Some organizations found it difficult to apply the QA criteria to their offices missions, especially since the majority of HQ work is administrative in nature.

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The Department is in a unique position to use the momentum from the survey to strengthen QAPs throughout the Department. The Deputy Secretary might consider this opportunity to strongly encourage Departmental Elements to document and apply quality to their work processes and products. Further, the QA effectiveness initiative might reinforce for executive leadership the necessity to take the next logical steps in implementing quality complex-wide. To that end, the original QA working group proposed a path forward for continuing and supporting the work done thus far.

When the working group developed the reporting guidance for the survey, its intent was to methodically evaluate QA implementation by establishing a baseline for future analyses. The working group envisioned a process whereby QA maturity and effectiveness would be measured against a proven criteria set. An effectiveness review team would borrow the best practices of successful evaluation models to tailor a process that would capture the unique challenges of the DOE environment. The breadth and depth of these effectiveness analyses would increase gradually through a proposed multi-year graded strategy. These review criteria would continuously evolve as the QA working group learns more about individual programs and how quality is interpreted and applied. Ultimately, QAPs would be assessed and the results distributed for DOE senior management and stakeholders.

However the Secretary chooses to proceed, it should be evident that quality assurance cannot be a static managerial notion—documented once, applied, and forgotten. It is an ongoing and evolving process that requires constant attention and implementation from top management down. The results of this survey highlight for the Department's executive leadership the progress made by HQ and the Field thus far in implementing quality. How these results are utilized may help determine the future strength and excellence of the quality culture within the Department.

Appendix A: Distribution of Quality Assurance Reporting Guidelines

(PRIMARY DOE ORGANIZATIONS TO WHICH DOE O 414.1C IS APPLICABLE)

Offices responding to the survey are marked with ☒.

Offices marked with ☒ have been subsumed into the new HSS organization, which will develop its own Quality Assurance Program plan in FY 2007. Note: The Office of Environment, Safety and Health as well as the Office of Security and Safety Performance Assurance submitted responses.

- ☐ Office of the Secretary
- ☒ Chief Financial Officer
- ☒ Chief Information Officer
- ☒ Departmental Representative to the Defense Nuclear Facilities Safety Board
- ☒ Defense Programs (now NNSA)
- ☒ Office of Energy Efficiency and Renewable Energy
- ☒ Office of Environmental Management
- ☒ Office of Fossil Energy
- ☒ Office of Science
- ☒ Office of Environment, Safety and Health
- ☒ Energy Information Administration
- ☒ Office of Congressional and Intergovernmental Affairs
- ☐ Office of General Counsel
- ☒ Office of Policy and International Affairs
- ☒ Office of the Inspector General
- ☒ Office of Human Capital Management
- ☒ Office of Intelligence and Counterintelligence
- ☒ Office of Legacy Management
- ☒ Office of Management
- ☒ Office of Nuclear Energy, Science and Technology
- ☒ Office of Electricity Delivery and Energy Reliability
- ☒ Office of Civilian Radioactive Waste Management
- ☒ Office of Security and Safety Performance Assurance
- ☒ Office of Hearings and Appeals
- ☒ Office of Economic Impact and Diversity
- ☒ Office of Public Affairs
- ☒ Southeastern Power Administration
- ☒ Southwestern Power Administration
- ☒ Western Area Power Administration

Appendix B: Data Summary Responses by Reporting Offices

1. Quality Assurance Program (QAP)/General Requirements (Criterion 1)

- a. Has the Secretarial Office QAP for HQ been developed and approved per DOE Order 414.1C?
- b. Have the Field Office QAPs been developed and approved per DOE Order 414.1C?
- c. Have the necessary procedures been written and approved for implementation of the QAP?

Inquiry	HQ Elements Responding Positively	Field Elements Responding Positively
QAPs developed and approved	65%	77%
Implementing procedures written and approved	35%	49%

2. Flow Down of QA Requirements (Criterion 1 and 7)

- a. Has the contracting officer directed that DOE Order 414.1C be added and incorporated into all applicable contracts?
- b. Has DOE approved contractor QAPs incorporating DOE Order 414.1C?

Inquiry	Affirmative Response
Contractor directed to incorporate DOE O 414.1C	62%
Approved QAPs incorporating DOE O 414.1C	51%

3. Management, Training & Qualifications (Criterion 2)

- c. Does the QAP identify the senior management position(s) and reporting structure/relationship for the person specifically assigned the responsibility to develop, approve, and implement QAPs governing the work of their organization(s) and their contractors?
- d. Does the QAP identify delegation of QAP authorities from the senior manager position to an individual (e.g., QA Manager) with authority and qualifications (i.e., QA Functional Area Standard per the DOE Technical Qualification Program, or other qualification programs) needed to carry out responsibilities (with QA performance elements in their performance plans) including participation in the establishment of requirements, development, assessment, oversight, and implementation of programs, projects and goals and contracts?

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Inquiry	HQ Elements Responding Positively	Field Elements Responding Positively
Responsible senior manager identified	69%	89%
Delegated to qualified individual	62%	74%

4. Assessments and Improvements (Criterion 3, 9 and 10)

- a. Does the QAP establish Independent Assessment and Management Assessment processes with approved implementation schedules to measure the effectiveness of QA policy and program implementation in your organization?
- b. Does the QAP establish a process to identify and track actions resulting from assessments and ensure necessary improvements are achieved (i.e., a feedback and improvement or corrective action process)?

Inquiry	HQ Elements Responding Positively	Field Elements Responding Positively
Assessment processes and schedule identified	65%	86%
Corrective action tracking system in place	65%	91%